SHANGHAI CHINASTAR CORP

No.283, Che Xin Rd, Che Dun Zhen, Song Jiang County, Shanghai, China
C/O: 11F, No.201, Nanking E.Rd., Sec 3, Taipei, Taiwan, R.O
Tel:886-22713-6677 Fax:886-22546-2480

JAN - 9 2001

510(K) summary

This is a summary of the 510(K) safety and effectiveness information being Submitted in accordance with the requirement of SMDA 1990 and 21CFR 807.92

The assigned 510(K) number is: K003675

1. Submitter

Mr. Lee Hung Te Che
Shanghai China Star Corp
No. 283, Che Xing Road, Che Dun Zhen, Song Jiang County
Shanghai, China

Date summary prepared: September18th, 2000

2. Name of device

Shanghai China Star Corp
Powdered Blue Nitrile Patient Examination Glove

3. Predicate device

Brightway Brand Blue Nitrile Examination Gloves (Powdered)

4. Device description

Class I Powdered Nitrile Examination Glove, 80LZA powdered with absorbable dusting powder that meets all requirements of ASTM D 3578-95 except unaged ultimate elongation.

5. Intended use

A powdered patient examination glove is a disposable device made of natural rubber latex or synthetic material that bears powder to facilitate donning and is intented to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants

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6. Comparison to Predicate devices:

Shanghai China Star Corp Nitrile Powderfree Patient Exam Glove is substantially equivilant in safety and effectiveness to the Brightway Brand Blue Nitrile Examination Gloves (Powdered).

COMPARISON BETWEEN PREDICATE AND PROPOSED DEVICE

PREDICATE DEVICE CHARACTERISTICS		PROPOSED DEVICE CHARACTERISTICS	
Overall length	240 mm	Overall length	240mm
Width (size medium)	89 mm	Width (size medium)	89mm
Palm thickness	0.15mm	Palm thickness	0.15
Finger thickness	0.18mm	Finger thickness	0.18
Tensile strength pre aging min	21mpa	Tensile strength pre aging	21mpa
Tensile strength after aging min	16mpa	Tensile strength after aging	16mpa
Ultimate elongation pre aging min	500	Ultimate elongation pre aging	500
Ultimate elongation after aging min	500	Ultimate elongation after aging	500
Skin irritation test	Passes	Skin irritation test	passes
Skin sensitization	passes	Skin sensitization	passes

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalance are as follows

The standards used by Shanghai Chinstar Corp to determine substantial equilvalance are based on ASTM D 3578-95 and ASTM D 5250-92. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0 and S-4 AQL 2.5

Primary Skin Irritation and Skin Sensitization (allergic contact dermititis) testing were also conducted with results showing no primary skin irritation or sensitization reactions.

There are no special labeling claims and we do not claim our gloves to be hypoallergenic.

Shanghai Chinastar Corp operates in compliance with the FDA's GMP

8. Discussion of Clinical Tests Performed:

Not applicable-There is no hypoallergnic claim

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9. Conclusions

Shanghai China Star Corp. Nitrile Powdered Patient Examination Gloves are substantially equivilant to Brightway Brand Blue Nitrile Examination Gloves Powdered. Also, Shanghai China Star Corp. Nitrile Powdered Patient Examination Gloves conform fully to ASTM D-3578-95 (execpt ultimate elongation), but the gloves elongation is far above the minimum required by ASTM D 5250-92. Also, the gloves comply with FDA pinhole requirements, biocompatibility requirements, and labelling claims. There are no safety/efficacy issues or new claims from the "substantial equivalence" products sited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2001

Shanghai Chinastar Corporation
C/O Mr. Ned Devine, Jr
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, Southeast
Grand Rapids, Michigan 49548

Re: K003675
Trade Name: Shanghai Chinastar Powdered Blue Nitrile Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: December 21, 2000
Received: December 26, 2000

Dear Mr. Devine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SHANGHAI CHINASTAR CORP

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September 18th, 2000

Indications For Use Statement

Applicant : SHANGHAI CHINA STAR CORP
510(K) number :
Device name : Shanghai Chinastar Powdered Blue Nitrile Examination Gloves

Indications for use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner

Lee Hung Te Che
President
Shanghai Chinastar Corp

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003675